II. REMARKS

Reconsideration of the present application as amended, and in view of the following remarks, is respectfully requested.

Claims 8-11, 13-14, 16, 20, 22-24, 29-30, 32-38 and 40-45 are currently pending. Claims 8, 20, 29-30, 32, 35 and 44 have been amended without prejudice. Claims 1-7, 12, 15, 17-19, 21, 25, 27-28 and 31 have been canceled without prejudice. Claim 39 has been previously withdrawn.

Claim 8 has been amended to incorporate certain subject matter from claim 15. Claim 20 has been amended to incorporate certain subject matter from claims 8 and 31. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

A. Rejection under 35 U.S.C. § 112

Claim 35 was rejected under 35 U.S.C. §112, second paragraph, on the grounds that the term "rubber-like polymer" does not set out the metes and bounds of the claim. In response, claim 35 has been amended without prejudice to remove the phrase "rubber-like".

Claim 44 was rejected on the grounds that the limitation, "softening ester" lacks sufficient antecedent basis in claim 23. In response, claim 44 has been amended without prejudice to recite "softening agent", rather than "softening ester" in order for the claim to have sufficient antecedent basis.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. §112, second paragraph rejections.

B. Rejection under 35 U.S.C. § 103 over Kogan et al.

Claims 1, 2, 4-11, 13-16, 20-24, 26, 27, 29-38 and 40-45 were rejected under 35 U.S.C. § 103(a), "as being unpatentable over U.S. Patent No. 4,910,205 [hereinafter 'Kogan et al.']."

This rejection is traversed. It is respectfully submitted that Kogan et al. fail in the very least to teach or suggest a method of maintaining a transdermal delivery system in contact with the skin of a patient for at least 5 days wherein the transdermal delivery system maintains a "plasma level of loratadine at steady state from about 1 to about 3 ng/ml" and wherein the transdermal delivery system provides a "mean relative release rate of from about 2.8 $\mu g/cm^2/hr$ to about 16.2 $\mu g/cm^2/hr$ at 24 hours; from about 2.3 $\mu g/cm^2/hr$ to about 13.7 $\mu g/cm^2/hr$ at 48 hours; from about 2.0 $\mu g/cm^2/hr$ to about 11.9 $\mu g/cm^2/hr$ at 72 hours; and a mean relative release rate of from about 1.8 $\mu g/cm^2/hr$ to about 9.9 $\mu g/cm^2/hr$ at 96 hours" as recited in present claim 8.

Further Kogan et al. fails to teach or suggest, a transdermal delivery system which maintains a "plasma level of loratadine at steady state from about 1 to about 3 ng/ml" and which provides a "mean relative release rate of from about 2.8 $\mu g/cm^2/hr$ to about 16.2 $\mu g/cm^2/hr$ at 24 hours; from about 2.3 $\mu g/cm^2/hr$ to about 13.7 $\mu g/cm^2/hr$ at 48 hours; from about 2.0 $\mu g/cm^2/hr$ to about 11.9 $\mu g/cm^2/hr$ at 72 hours; and a mean relative release rate of from about 1.8 $\mu g/cm^2/hr$ to about 9.9 $\mu g/cm^2/hr$ at 96 hours" as recited in present claim 20.

It is noted that the Examiner has acknowledged that Kogan et al. do not teach the specific delivery profile of loratadine. See page 4, 1st full paragraph of the Office Action. It is respectfully submitted that the in view of the Kogan reference, one skilled in the art would not be motivated to formulate a loratadine transdermal system which provides the specific plasma level at steady state and the particular release profiles at the specific time points as recited in claims 8 and 20. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection over Kogan et al.

C. **Rejection under 35 U.S.C. § 103 over Aslanian et al. in view of Miranda et al.**

Claims 1, 2, 4-11, 13-16, 20-24, 26, 27, 29-38 and 40-45 were rejected under 35 U.S.C. § 103(a), "as being unpatentable over U.S. Patent No. 6,103,735 (hereinafter 'Aslanian et al.') in view of U.S. Patent No. 5,091,186 (hereinafter 'Miranda et al.')".

This rejection is traversed. In the Office Action, the Examiner acknowledged that Aslanian et al. do not teach the delivery profile as claimed in claims 1-16, and stated that Miranda et al. describe a transdermal drug delivery device to deliver drugs at therapeutically effective rates for about 20-28 hours (citing the abstract; col. 6, lines 4-20, col. 7, lines 29-40).

It is respectfully submitted that Aslanian et al. describe combination compositions (e.g., including (i) a therapeutically effective amount of at least one neurokinin antagonist; (ii) a therapeutically effective amount of at least one H3 antagonist and (iii) a therapeutically effective amount of at least one H1 antagonist) for treating or preventing allergic rhinitis and other respiratory disease. Loratadine is listed as an H1 antagonist.

It is respectfully submitted that Miranda et al. describe transdermal delivery systems in which drug delivery is biphasic. Miranda et al. describe the biphasic delivery as including a delivery phase (e.g., typically of 10 to 14 hours) followed by a secondary phase, (e.g., which virtually no drug is delivered). Miranda et al. describe that "the total dosing period is about 20 to 28 hours, most preferably, ... about 24 hours. The patch may thus be removed and replaced every day at about the same time." See column 7, lines 33-40.

It is respectfully submitted that one or ordinary skill in the art would not be motivated to provide a method of treatment comprising a transdermal delivery system having mean relative release rates over a 96 hour period as recited in claim 8, or the transdermal delivery system providing mean relative release rates over a 96 hour period as recited in claim 20, as Miranda et al describe a "a biphasic transdermal delivery device

for delivering a drug at therapeutically effective rates during an initial delivery phase of about 10 to 14 hours, but which during a subsequent, secondary phase, delivers substantially no drug ..." See column 2, lines 53-58.

Further, one of ordinary skill in the art would not be motivated to maintain the transdermal delivery system described in Miranda et al. in contact with the skin of the patent for at least 3 days as recited in independent claims 8 and 20, as Miranda et al. describe virtually no drug being delivered after the delivery phase of typically 10 to 14 hours. According to Miranda, a new patch must be applied in order to receive additional therapy.

Further, Aslanian et al. and Miranda et al. do not exemplify loratadine transdermal devices, and do not provide any teaching or suggestion of any desired pharmacokinetic parameters for loratadine. Therefore, it is respectfully submitted that these references do not teach or suggest loratadine devices which provide the presently claimed pharmacokinetic parameters.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the obviousness rejection over Aslanian et al. in view of Miranda et al.

D. Rejection under 35 U.S.C. § 103 over Kogan et al. in view of Hille

Claims 37, 38, 44 and 45 were rejected under 35 U.S.C. § 103(a) "as being unpatentable over US '205 [Kogan et al.] in view of U.S. Patent No. 5,240,711" (hereinafter "Hille et al.").

This rejection is traversed. It is respectfully submitted that Hille et al. fail to cure the deficiencies of Kogan et al. as presented above, as Hille at al. do not teach or suggest the specifically claimed pharmacokinetic parameters for loratadine transdermal systems as recited in claims 8 and 20.

Further, it is respectfully submitted that these references are improperly combinable. Kogan et al. is specifically directed to loratadine transdermal systems for the treatment of allergic reactions and Hille et al. is directed to buprenorphine transdermal systems for the treatment of pain. There is no teaching or suggestion to selectively take certain elements from Hille et al. and combine only those elements with Kogan et al.

Therefore, Applicant respectfully requests reconsideration and withdrawal of the obviousness rejection over Kogan et al. in view of Hille et al.

E. Rejection under 35 U.S.C. § 103 over Aslanian et al. and Miranda et al. in view of Hille et al.

Claims 37, 38, 44 and 45 were rejected under 35 U.S.C. § 103(a) "as being unpatentable over US '735 ['Aslanian et al.'] in view of US '186 ['Miranda et al.'] as applied to claims 1-16, 20-38, and 40-45, and further in view of '711 ['Hille et al.']"

This rejection is traversed. It is respectfully submitted that Hille et al. fail to cure the deficiencies of the combination of Aslanian et al. in view of Miranda et al. as presented above, as Hille at al. do not teach or suggest the specifically claimed pharmacokinetic parameters for loratadine transdermal systems as recited in claims 8 and 20.

Further, it is respectfully submitted that these references are improperly combinable. Aslanian et al. is specifically directed to compositions for treating allergic rhinitis and repiratory diseases and Hille et al. is directed to buprenorphine transdermal systems for the treatment of pain. There is no teaching or suggestion to selectively take certain elements from Hille et al. and combine only those elements with Aslanian et al., further in view of Miranda et al.

III. CONCLUSION

In view of the foregoing, Applicants believe that all claims are now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance prosecution of the present application. An early and favorable action is earnestly solicited.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By:_____
Robert J. Paradiso
Reg. No. 41,240

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940